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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,329	03/18/2005	Gabor Butora	21054P	6299
210	7590	11/13/2006	EXAMINER	
MERCK AND CO., INC P O BOX 2000 RAHWAY, NJ 07065-0907			NOLAN, JASON MICHAEL	
			ART UNIT	PAPER NUMBER
			1626	

DATE MAILED: 11/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/528,329	Applicant(s) BUTORA ET AL.	
	Examiner Jason M. Nolan, Ph.D.	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 02 October 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) 3,4,12-15,20,21 and 24-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,5-7,9,10,16-19,22 and 23 is/are rejected.
- 7) ☒ Claim(s) 8 and 11 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>1/3/2006</u> | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

**Claims 1-27** are currently pending in the instant application. No amended or new claims are presented.

#### *Priority*

This application is a 371 of PCT/US03/34009. Acknowledgement is made of Applicants' claim for benefit of US Provisional Patent Application 60/422,268, filed on October 30, 2002. Said claim has been made in the ADS and/or in the first paragraph of the Specification.

#### *Information Disclosure Statement*

Applicants' information disclosure statement (IDS), filed on January 3, 2006 has been considered. Please refer to Applicants' copy of the 1449 submitted herein.

#### *Response to Restriction*

Applicants' election with traverse of **Group I, Claims 1-23**, drawn to products of the Formula I, wherein **W** = C, **n** = 1 (there are two n's: so **n** = 1, it is a 6-membered ring), **X** and **R<sup>1</sup> & 5-12** are as defined, and **R<sup>3</sup> & R<sup>4</sup>** are joined together to form a ring is acknowledged. Applicants' traversal is based on the following arguments: the compounds share common structural features and given the commonality of the subject matter, examination does not place a serious search burden on the Examiner.

In response, Examiner points out that there is a lack of unity since the technical feature is not a special technical feature because it fails to define a contribution over the prior art (see v. Braun, J. Ber. 1909, 42, 2035-57). The Examiner also points out that an attempt to search even the elected group is a serious search burden such that a

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comprehensive search is not possible. Preliminary searching revealed over 19,000 compounds in less than 39% of the CAPLUS database.

Therefore the Restriction Requirement is maintained and FINAL.

As a result of this restriction requirement, the remaining subject matter of **Claim 1 (in part) & Claims 3, 4, 12-15, 20, 21, 24-27** is withdrawn from further consideration as being drawn to non-elected subject matter.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

**Claims 1, 2, 5, 9, 16-19 & 23** are rejected under 35 U.S.C. 102(a) as being anticipated by Matsuoka *et al.* (WO 2002048117 A1, published 6/20/2002, filed 12/5/2001). Disclosed is compound RN 437998-96-4: wherein  $R^3$  &  $R^4$  form a 2,3-dihydro-1H indene, X is  $-\text{CONR}^{10}$ ,  $R^2$  is  $\text{C}_6\text{-phenyl}$  - substituted with  $\text{NR}^9\text{R}^{10}$ , and  $R^{5-12}$  are H.

**Claims 1, 2, 16-19 & 23** are rejected under 35 U.S.C. 102(e) as being anticipated by Ito *et al.* (WO 2003000677 A1, published 1/03/2003, filed 6/17/2002, priority to US Provisional 6/26/2001). Disclosed are compounds RN 480999-78-8: wherein  $R^3$  &  $R^4$  form 2,3-dihydro-1H-indene,  $X$  is NH,  $R^2$  is phenyl, substituted with  $NH_2$ , and  $R^{1, 5-8, 11 \text{ \& } 12}$  are H; RN 475151-60-1 & RN 475151-51-2: wherein  $R^3$  &  $R^4$  form 2,3-dihydro-benzofuran,  $X$  is NH-CO-,  $R^2$  is heterocyclic ring - substituted by a heterocyclic ring, and  $R^{1, 5-8, 11 \text{ \& } 12}$  are H; and RN 475151-62-3: wherein  $R^3$  &  $R^4$  form 1,3-dihydro-isobenzofuran,  $X$  is NH-CO-,  $R^2$  is heterocyclic ring - substituted by a  $C_5$ -cycloalkyl ring, and  $R^{1, 5-8, 11 \text{ \& } 12}$  are H.

**Claims 1, 9, 16-18 & 23** are rejected under 35 U.S.C. 102(b) as being anticipated by Effland *et al.* (US 4,166,119, published 8/28/1979). Disclosed are compounds RN 71918-10-0 and RN 71918-11-1: wherein  $R^3$  &  $R^4$  form 2,3-dihydro-benzofuran,  $X$  is O,  $R^2$  is  $C_0$ -phenyl, and  $R^{1, 5-8, 11 \text{ \& } 12}$  are H.

**Claims 1, 9, 16-18 & 23** are rejected under 35 U.S.C. 102(b) as being anticipated by Moltzen *et al.* (EP 518805: see US 5665725, published 9/9/1997). Disclosed are compounds RN 147372-50-7: wherein  $R^3$  &  $R^4$  form 1,3-dihydro-isobenzofuran,  $X$  is O,  $R^2$  is  $C_0$ -phenyl, and  $R^{1, 5-8, 11 \text{ \& } 12}$  are H; and RN 147818-69-7: wherein  $R^3$  &  $R^4$  form 1,3-dihydro-isobenzofuran,  $X$  is O,  $R^2$  is  $C_0$ -heterocycle (benzothiofuran), and  $R^{1, 5-8, 11 \text{ \& } 12}$  are H.

**Claims 1, 6, 7, 9, 16-18 & 23** are rejected under 35 U.S.C. 102(a) as being anticipated by Pairet *et al.* (US 2002169181, published 11/14/1997). Disclosed are

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compounds RN 173941-22-5: wherein  $R^3$  &  $R^4$  form 1,3-dihydro-isobenzofuran,  $X$  is  $CH_2-N(Me)CO$ ,  $R^2$  is  $C_0$ -phenyl,  $R^1$  is  $Ph(Cl)_2$ , and  $R^{5-8,11 \text{ \& } 12}$  are H.

**Claims 1, 9, 10, 16-18 & 23** are rejected under 35 U.S.C. 102(e) as being anticipated by Marzabadi *et al.* (WO 2004004714 A1, published 1/15/2004, filed 7/3/2003, priority to US Provisional 7/3/2002). Disclosed are compounds RN 644975-02-0, RN 644975-03-1, RN 644975-04-2, RN 644975-06-4, RN 644974-82-3, RN 644974-31-2, RN 644974-32-3, RN 644974-33-4, RN 644974-37-8, RN 644974-42-5, RN 644974-53-8, RN 644974-57-2, RN 644974-69-6, and RN 644974-73-2.

**Claims 1, 6, 7, 9, 10, 16-18 & 23** are rejected under 35 U.S.C. 102(b) as being anticipated by Jacobs *et al.* (EP 630887 A1, published 12/28/1994). Disclosed is compound RN 161609-64-9.

**Claims 1, 6, 7, 9, 10, 16-18 & 23** are rejected under 35 U.S.C. 102(b) as being anticipated by Hale *et al.* (WO 9417045 A1, published 8/4/1994). Disclosed are compounds RN 164328-35-2, RN 164328-41-0, RN 164328-84-1, RN 164328-85-2, RN 164328-94-3, RN 164328-97-6, RN 164328-98-7.

**Claims 1, 6, 7, 9, 10, 16-18 & 23** are rejected under 35 U.S.C. 102(b) as being anticipated by MacCoss *et al.* (WO 9429309 A1, published 12/22/1994). Disclosed are compounds RN 167484-54-0, RN 167484-66-4, RN 16748468-6, RN 167484-69-7, RN 167484-70-0, RN 167484-71-1, RN 167484-73-3, RN 167484-74-4, RN 167484-75-5, RN 167484-76-6, RN 167484-78-8, and RN 167484-81-3.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

**Claim 22** is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims must, under modern claim practice, stand alone to define an invention, *Ex parte* Fressola, 27 USPQ 2d 1608 (1993). The instant claim does not provide a structure (or chemical name) for "title compounds of the Examples" and one must refer back to the specification to define the claimed invention.

***Claim Objections***

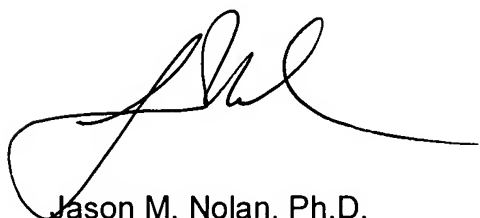
**Claim 1** is objected to for containing non-elected subject matter. Appropriate correction is required.

**Claims 8 & 11** are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.


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***Telephone Inquiry***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jason M. Nolan, Ph.D.** whose telephone number is **(571) 272-4356** and electronic mail is **Jason.Nolan@uspto.gov**. The examiner can normally be reached on Mon - Fri (9:00 - 5:30PM). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Joseph M<sup>c</sup>Kane** can be reached on **(571) 272-0699**. The fax phone number for the organization where this application or proceeding is assigned is **571-273-8300**. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Jason M. Nolan, Ph.D.  
Examiner  
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Date: November 8, 2006